REMARKS

Claims pending following entrance of this amendment are 1, 4-27, 29, 30, and 32-37.

All claims as they existed prior to this response were rejected.

Claim Rejections:

1. Enablement:

Claims 1, 4-27, 29, 30, and 32-35 and 37 were acknowledged as being enabling for providing a patient with a medication with an odorous marker additive and analyzing for the marker by way of electronic nose technology. Without conceding that there is any merit to the grounds for rejection, in order to advance prosecution in this case, all claims are herein amended to recite these limitations and therefore, this ground for rejection may now be withdrawn.

2. Indefiniteness:

Claims 1, 4-27, 29, 30, 32-35 and 37 were rejected as being indefinite due to the inclusion of the term "almost immediately". This term has been deleted from all of the claims. Accordingly, this ground for rejection may now be withdrawn.

Claim 35 was rejected as being indefinite for reciting the term "Generally Recognized as Safe compound". This ground for rejection is traversed. This is a term of art and is defined by the US Federal Food and Drug Administration, see:

http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm

Accordingly, reconsideration and withdrawal of this ground for rejection is respectfully requested.

3. Obviousness – 35 USC 103:

Claims 1, 8, 9, 12-20, 23-27, 29 and 32 and 35 were rejected as unpatentable over Kell (5,776,783) in view of Katzman (5,962,335).

This ground for rejection is traversed. Kell discloses detection of a particular marker (benzodiazepine) added to medication (methadone) in the urine. The Office provides no support for its assertion that benzodiazepine or its metabolites could or would be detected in a patient's breath. Katzman detects an isotopically labelled active therapeutic agent in a patient's breath. The current claims specifically exclude use of a marker that is part of the active therapeutic agent itself. Katzman does not disclose detection of metabolites of a marker that is not part of the active therapeutic agent. Katzman is also directed to metabolic studies in which there can be no doubt about whether the active therapeutic agent has been taken, thus the detection is being conducted for reasons wholly unrelated to determining patient compliance or not in taking a medication. Those skilled in the art would have no reason to combine these references and the Office is engaging in impermissible hind-sight reconstruction of the cited art in light of what is taught and claimed in the present application.

With regard to claim 35, it is stated that the present application does not disclose the marker being a GRAS compound as claimed.

This statement is simply not comprehended. In the subject application as published, paragraph 0041 reads as follows:

[0041] The substances referred to as "olfactory markers" herein are detected by their physical and/or chemical properties, which does not preclude using the medication itself as its own marker. Preferable markers include, but are not limited to, the following: trans-Anethole (1-methoxy-4-propenyl benzene)—anise; Benzaldehyde (benzoic aldehyde)—bitter almond; Butyl isobutyrate (n-butyl2,methyl propanoate)—pineapple; Cinnamaldehyde (3-phenylpropenal)—cinnamon; Citral (2-trans-3,7-dimenthyl-2,6-octadiene-1-al)—citrus; Menthol (1-methyl-4-isopropylcyclohexane-3-ol)—menthol; and alpha-Pinene (2,6,6-trimethylbicyclo-(3,1,1)-2-

heptene)—pine. These markers are preferred since they are used in the food industry as flavor ingredients and are permitted by the Food and Drug Administration as indicated in the Code of Federal Regulations, Chapter 21, et. sec. Moreover, these markers are classified **"generally recognized as safe"** by the Flavor and Extract Manufacturer's Association. These markers are also all natural products and single individual compounds, not mixtures, to enhance detection and represent a variety of chemical structures to enhance differentiation in detection devices. They are generally poorly soluble in water which enhances their volatility and detection in the breath."

There is a definition of what is a "generally recognized as safe compound" provided by the FDA, see the link provided above. GRAS is merely an acronym for the term "generally recognized as safe". The pharmaceutically active compound, benzodiazepine, used according to Kell as the marker for compliance in taking methadone does not qualify as a GRAS compound – see **Title 21: Food and Drugs,** PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE, which lists hundreds if not thousands of compounds, and benzodiazepine is not in this list. An electronic link to the relevant title is provided here for the convenience of the Office:

http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=786bafc6f6343634fbf79fcdca7061e&rgn=div5&view=text&node=21:3.0.1.1.13&idno=21

This ground for rejection may therefore be withdrawn.

For each of the following rejections, the Kell + Katzman combination of references is used as the basis for the rejection of additional claims, standing alone, or in combination with an additional reference. It is urged that the defects discussed above with respect to the Kell + Katzman combination of references are not cured by what is stated in any of these additional rejections and each of these additional cited references:

Claims 4, 5, and 21 are rejected as being unpatentable over Kell in view of Katzman and further in view of Payne (WO98/39470).

Claims 6, 10, 11, and 34 are rejected as unpatentable over Kell/Katzman as discussed above, and further in view of Forester (4,762,719).

Claim 7 is rejected as being obvious in light of the Kell/Katzman combination as discussed above, and further in view of Guth (4,353,869).

Claim 22 is rejected as obvious in light of Kell/Katzman and further in view of Ueda.

Claim 30 is rejected as obvious over Kell/Katzman as discussed above.

Claim 33 is rejected as unpatentable over the Kell/Katzman combination.

Claim 37 is rejected as being unpatentable over Kell/Katzman and in view of Phillips (5,220,919).

Accordingly, this ground for rejection should be reconsidered and withdrawn with respect to all of the claims in this application.

4. Non-statutory Obviousness-Type Double Patenting:

Claims 1, 4-9, 12-18, 20, 23-27 were provisionally rejected on the ground of non-statutory obviousness-type double patenting in light of claims 22-25, 29-31 and 34-42 of co-pending application USSN 11/097,647. Assuming that the response in this case resolves all other grounds for rejection, in order to achieve allowance in this case, the Applicant may either cancel claims in the daughter application which might form the basis of a double patenting rejection, or file a Terminal Disclaimer. It is respectfully requested that this concern be held in abeyance until claims in one or the other of these applications are otherwise in condition for allowance.

Conclusion:

It is respectfully urged that all grounds for rejection of the claims in the present application have been addressed and overcome in this Submission Under 37 CFR 1.114. Should there be remaining issues of concern to the Examiner, the courtesy of an in-person interview with the undersigned, in order to resolve any remaining concerns, is respectfully requested.

Respectfully submitted,

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